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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

August 20, 2002

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments
Docket No. 98N-0359

Dear Sir or Madam:

The following comments are submitted by The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA") in response to the request for comments on planned Program Priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for Fiscal Year 2003 (October 1, 2002 to September 30, 2003). 67 Fed. Reg. 42272 (June 21, 2002). Our comments are focused on proposed priorities relating to the regulation of cosmetics by CFSAN. Although we have designated some matters that should become (or remain) "A List" Priorities, we stress that all six matters listed in this document are extremely important to the industry and should receive attention by FDA during FY2003.

CTFA is the national trade association representing the cosmetic industry. Founded in 1894, CTFA has almost 600 members involved in formulating, manufacturing, distributing and marketing personal care products. Our members are responsible for manufacturing or distributing the vast majority of personal care products sold in the United States. Approximately one-half of our member companies are active members that manufacture or distribute cosmetics, toiletries and fragrances. The remaining one-half are associate members that provide goods, such as cosmetic raw materials, or services to manufacturers or distributors.

The cosmetic industry takes pride in its strong safety record and long history of successful self-regulation. Our self-regulatory programs are not only effective, but save scarce government resources. Working with CFSAN and specifically with the Office of

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Cosmetics and Colors within CFSAN, CTFA has supported many voluntary self-regulatory programs, such as the Cosmetic Ingredient Review (CIR), that have helped ensure the availability of a wide variety of safe cosmetic products. In turn, FDA's support for and participation in these voluntary programs, backed by an effective regulatory presence, have resulted in an industry that has consistently been recognized by FDA to be "as safe as they come."

We recognize that over the past year FDA has been faced with many new responsibilities to protect the American public from threats of terrorism that could be directed against the products that FDA regulates, and that these new duties have been added to CFSAN's already substantial responsibilities to ensure a safe food supply. We offer our full cooperation to FDA in these efforts. However, we also believe it remains as important as in the past that FDA continue to maintain a strong cosmetic regulatory program within CFSAN.

As in the past, CTFA will continue to urge Congress to maintain adequate funding for cosmetic regulation in CFSAN. We strongly believe that a fully-funded and credible cosmetic regulatory program is necessary to ensure that all cosmetic products meet the high standards of safety that the public, the FDA and our own industry demand.

The following are CTFA's proposals for issues to be included in CFSAN's 2003 Program Priorities:

1. Allow the Industry to Use "Colour Index" Nomenclature for Color Additives

It has become essential that FDA permit the use of nomenclature for color additives that is recognized and used throughout most of the world outside the United States. This involves use of the Colour Index or "CI" number instead of the "FDA" nomenclature required only in the United States. Designation of colorants on cosmetic product labels, using the international Colour Index number, was begun in Europe in 1993 to aid in lessening the confusion of providing "common names" in many different languages. Since that time, other countries throughout the world have accepted this approach, rather than requiring their own translations. CTFA and Colipa, the European cosmetic trade association, have both previously requested that FDA recognize the "CI" nomenclature, but no action has been taken on those requests.

This matter has become more urgent because of action proposed by the Canadian authorities that will allow the use of CI or FDA nomenclature, but, if the FDA nomenclature is used, will require that it also be translated into French. Thus, instead of being able to list the color as CI 45380 on a U.S./Canadian harmonized cosmetic product, Red 22 would be required to be labeled as Red/Rouge 22 in Canada, nomenclature that would not be allowed in the U.S. or anywhere else.

The CI nomenclature has now become the international standard, and is recognized throughout the world as the appropriate way to designate color additives on the label. The FDA-required nomenclature has posed a significant barrier to international harmonization of cosmetic labels for some time. With the introduction of new Canadian requirements, it will now pose an even greater obstacle to label harmonization.

There would be no need to change the color additive names in the regulations, nor to change their marketing or trade names. The only change needed would be with the names allowed on the cosmetic product label. As this would not affect the regulation of cosmetics, nor what colorants are allowed in the U.S., the only possible concern FDA could have would be to ensure that the consumer and professionals needing such information would be able to adjust to recognizing the CI numbers as colorants, and being able to determine which FDA colorant these CI numbers reflect.

CTFA previously proposed a suitable transition period of consumer, industry, and medical profession education. During the transition period from FDA to CI nomenclature, CTFA would participate in the development of information to be provided to consumers, the industry, and the medical community explaining the change and providing cross-references for comparison purposes. These could also be put on FDA's cosmetics website. In fact, dual labeling has been encouraged for the past six years, so there has already been some opportunity for consumers to become acquainted with the CI nomenclature. We would be happy to work with FDA to develop a program that would be designed to more directly educate the necessary publics to this change.

FDA has a long history of supporting simplified nomenclature for color additives in the past. We urge FDA to take quick action to permit international harmonization of color additive nomenclature and to allow the use of CI numbers in the labeling of cosmetic products for sale in the United States.

For these reasons, we believe this matter should become an "A List" Priority for 2003.

2. Propose a Draft Guidance on AHA-containing Products

This matter has been on CFSAN's "A List" for the past two years. Action by FDA to require a label statement regarding the need to use sunscreen protection while using products containing alpha hydroxy acids (AHAs) and for a week after use was first requested by CTFA in a Citizen Petition filed in June, 2000.

Although CTFA first requested this matter be handled by a regulation, we fully support FDA's intentions to handle the matter by means of regulatory guidance, assuming the language proposed for AHA labeling is appropriate. We urge the Agency to complete this matter, and to propose a Guidance containing labeling language regarding the use of sunscreens during and after AHA use as proposed by CTFA. This is a matter that has the support of our membership, and should not present any significant regulatory or scientific obstacles to adoption.

This should remain an "A List" item if not completed before the end of FY2002.

3. Complete the Review and Listing of Carbon Black as a Color Additive for Cosmetic Use, in accordance with CTFA's Color Additive Petition (CAP 7C0208)

In the mid 1970's, FDA delisted Carbon Black as a colorant allowed for use in cosmetics, because of a lack of analytical information on the types and quantities of polynuclear aromatic hydrocarbons (PAHs) adsorbed on the Carbon Black. Some of the PAHs had been shown to be carcinogenic in animals, and without the ability at that time to show that there were no carcinogenic constituents, FDA felt that it had to delist Carbon Black under the Delaney requirements.

Following the advent of the "constituents policy," used for Green 5, an official at FDA suggested that CTFA should petition for the use of Carbon Black, and propose limits for the PAHs that would ensure that there would be no risk of cancer (risk less than 1/million). In 1987, CTFA filed a Color Additive Petition for Carbon Black, proposing a specification for total PAHs that would result in less than a 1/million risk, even if the entire PAH population was the most potent of the possible PAHs that could be present. From that time to the present, FDA has asked for additional information several times, and CTFA has responded several times.

Unfortunately, it appears that we have entered a cycle from which there is no exit. Every time FDA asks for additional information, CTFA supplies it. However, the Agency then takes a minimum of 180 days to review the information and requests additional information. This process has been going on now for about 15 years.

CTFA believes it is time for the agency to complete its review of the information in the petition, and to explain to CTFA exactly what, if anything, is still needed and why it is needed. We believe it is essential that this meeting be overseen by the appropriate FDA management staff, to ensure that the requests are consistent with what has been requested for other color additive petitions, and what is required by law.

CTFA believes that completion of the Carbon Black review should be an "A List" Priority to be completed in FY2003.

4. Adopt a More Efficient System for Adopting Changes in Cosmetic Product Labeling Nomenclature

We urge CFSAN to propose an amendment to 21 CFR Section 701.3(c)(2), replacing the current regulation with the following language, to facilitate the use of new cosmetic ingredient nomenclature as it is developed:

In the absence of a name specified in §701.30, or specifically adopted by the Food and Drug Administration for the purpose of labeling cosmetic products and published on the Food and Drug Administration's Center for Food Safety and Applied Nutrition's Cosmetic website, http://www.cfsan.fda.gov/~dms/cos-toc.html, the name adopted for that ingredient in the following compendia, listed in order as the source to be utilized:

(i) The most current edition, including supplements, of the International Cosmetic Ingredient Dictionary and Handbook, Cosmetic, Toiletry, and Fragrance Association, Inc., Washington, DC, (available from the Cosmetic, Toiletry, and Fragrance Association, Inc., 1101 17th Street, N.W., Washington, DC 20036, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, DC 20408).

(ii) The most current edition, including supplements, of the United States Pharmacopeia, (available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, DC 20408).

(iii) The most current edition, including supplements, of the National Formulary, (available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, DC 20408).

(iv) The most current edition, including supplements, of the Food Chemicals Codex, (available from the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C Street S.W., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, DC 20408)

(v) The most current edition, including supplements, of USAN and the USP dictionary of drug names, (available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., suite 700, Washington, DC 20408).

This action would implement a "B List" Priority from 2001 and 2002, and should be given higher priority in 2003. Making this change will recognize that there are continual changes in the compendia cited, with about 2,000 new ingredients being added to the International Cosmetic Ingredient Dictionary and Handbook each year, for example, and will provide for stability in the adoption of nomenclature for industry to use on cosmetic labels. It also will enable the Food and Drug Administration, through review of the changes and additions in nomenclature made each year, to specify alternative names that must be used for labeling purposes, by publishing alternative names on the Center for Food Safety and Applied Nutrition's Cosmetic website.

Through its representative on the International Nomenclature Committee, which also includes a representative of the Canadian Government and the European Commission, FDA participates in the naming process and receives all information available on new ingredients to allow an independent decision as to the appropriateness of any particular name assignment. This process provides FDA with ample opportunity to prepare any alternative names that it believes should be used, and to have those listed on its website, prior to the publication of CTFA's Dictionary.

5. Implement the WEB-based, Interactive Voluntary Cosmetic Registration System (VCRP)

CTFA once again urges CFSAN to act as quickly as possible to implement enhancements to the Voluntary Cosmetic Registration System. This matter was on the B* list in the 2002 CFSAN Priorities, and we strongly believe this deserves the attention necessary for completion in 2003.

Progress has been made in recent months, and CTFA and FDA have worked cooperatively to establish plans for a testing period for the new system to begin in the early fall. We are hopeful that after this testing is complete and any necessary adjustments made, the program can be implemented. As before, CTFA is prepared to invest substantial effort to publicize the program among our membership and encourage full participation in the program.

6. Provide Sufficient Resources for Participation in International Harmonization Efforts

In addition to the urgent matter regarding color additive nomenclature harmonization noted above, CTFA believes it is very important for representatives of the Office of Cosmetics and Colors to be directly involved in international harmonization initiatives.

The cosmetic industry is a global industry, and it is critical that FDA be in a leadership role in discussions with other governmental bodies and industry in taking steps to encourage and facilitate the free flow of personal care products across international boundaries. Those with expertise in cosmetic products and cosmetic regulation from FDA must be involved in these meetings and discussions. We urge CFSAN to reconfirm its commitment to these efforts and provide sufficient resources to ensure its involvement in these international efforts.

Conclusion

CTFA appreciates the efforts by CFSAN and the Office of Cosmetics and Colors to consider the industry's views in developing the 2003 Priorities. Please feel free to contact us if further information is needed about these or other FDA or industry cosmetic programs as the 2003 Program Priorities are being prepared.

Respectfully submitted,

E. Edward Kavanaugh
President

cc: Joseph A. Levitt
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